

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

**MINNESOTA MINING AND
MANUFACTURING COMPANY, and
RIKER LABORATORIES, INC.,**

Civil No. 99-13 (MJD/JGL)

Plaintiffs,

ORDER

v.

ALPHAPHARM PTY. LTD.,

Defendant.

APPEARANCES

Allen M. Sokal, Esq., Jeffer Ali, Esq., Gregory Chopskie, Esq., and Mary Susan Howard, Esq., on behalf of Plaintiffs.

Bruce H. Little, Esq., and James K. Stronski, Esq., on behalf of Defendant.

JONATHAN LEBEDOFF, United States Magistrate Judge

The above-entitled matter came on for hearing before the undersigned Magistrate Judge of District Court on March 26, 2001, on Plaintiffs' Motion to Extend Dates (Doc. No. 92). The case has been referred to the undersigned for resolution of pretrial matters pursuant to 28 U.S.C. § 636 and D. Minn. LR 72.1.

I. INTRODUCTION

Minnesota Mining and Manufacturing Company ("3M") brought this patent infringement suit to enforce two patents that relate to the manufacture of flecainide acetate, the active ingredient in 3M's

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FDA-approved TAMBACOR™ drug product. U.S. Patent No. 4,650,873 (“the ‘873 patent”) describes and claims a process for making flecainide acetate, and U.S. Patent No. 4,642,384 (“the ‘384 patent”) covers chemical intermediates that are generated when flecainide acetate is made according to the process in the ‘873 patent. Before 3M could market flecainide acetate, it was required to obtain Federal Drug Administration (“FDA”) approval by filing a New Drug Application (“NDA”) containing evidence of the safety and efficacy of flecainide acetate.

When a generic manufacturer seeks to enter the market, it is permitted to “piggyback” on the NDA filed by the pioneer corporation by submitting an Abbreviated New Drug Application (“ANDA”), which Alphapharm tendered to the FDA in July 1998. In the ANDA, Alphapharm included a certification alleging that the ‘384 patent was invalid and not infringed, and Alphapharm sent 3M a notice of its challenge as required. When 3M subsequently filed suit, it automatically triggered a 30-month stay of FDA approval of Alphapharm’s ANDA.

3M contends in this lawsuit that Alphapharm infringed the ‘384 patent by filing its ANDA. Unlike typical patent infringement cases, Alphapharm has not yet marketed its product. Rather, 3M claims that the infringement consists of Alphapharm’s filing of the ANDA, including the certification. 3M also avers that the manufacture and sale of Alphapharm’s product in the United States would infringe the ‘873 patent. In response to 3M’s claims, Alphapharm denies infringing either

the '384 or the '873 patent and maintains that both patents are obvious and therefore invalid under 35 U.S.C. § 103.

In the present motion, Plaintiffs 3M and Riker Laboratories, Inc. (collectively "3M") seek an order under 21 U.S.C. § 355(j)(5)(B)(iii) extending the 30-month stay of approval by the FDA of Alphapharm's ANDA. The Hatch-Waxman Act places an affirmative duty on the parties in this case to expedite this suit to resolution before the expiration of the 30-month stay by the FDA. 3M avers that Alphapharm has violated this duty in three respects: by challenging jurisdiction in this District; by not timely responding to discovery requests, and consequently, concealing its true position in the case until recently; and by amending its ANDA to change its supplier of flecainide acetate. 3M explains that Alphapharm removed Maprimed from its application as the supplier, which fundamentally altered the central issue in this case and mooted considerable discovery and trial preparation. Thus, 3M seeks an extension of the 30-month stay.

Additionally, 3M moves for an order under D. Minn. LR 16.3 modifying the Pretrial Order by extending all dates six months. As grounds for the motion, 3M asserts that Defendant Alphapharm has violated its statutory duty to reasonably cooperate in expediting this suit. In particular, 3M charges that Alphapharm concealed certain contentions until just before the close of discovery in that Alphapharm did not reveal its bases for its validity and infringement contentions until

February 2001, approximately four months after 3M served its discovery requests and with only one month remaining in the discovery period. 3M also submits that Alphapharm's recently amended ANDA, dropping its previous supplier of flecainide acetate, Maprimed, altered the central infringement issue in the case. According to 3M, this act combined with Alphapharm's addition of Merck KGaA ("Merck") as a supplier in September 2000 mooted much of 3M's discovery and pretrial preparation because 3M had conducted extensive, almost exclusive discovery on Maprimed's process of manufacturing flecainide acetate. 3M claims that the change in suppliers has fundamentally altered what 3M must prove at trial.¹

Alphapharm responds that it amended its ANDA to include Merck in September 2000, but that 3M learned of the prospective amendment in May 2000. Moreover, Alphapharm contends that 3M learned of Alphapharm's intent to rely on Merck as its sole supplier in January 2001. Attempting to show prejudice, Alphapharm further argues that an extension in the pretrial schedule will delay the filing, hearing, and resolution of its impending summary judgment motion.

¹ 3M also charges Alphapharm with unjustifiably challenging personal jurisdiction. However, there is no evidence that Alphapharm's motion was frivolous, and the Court does not take a position on Alphapharm's exercise of a right granted by the Federal Rules of Civil Procedure.

II. MODIFICATION OF THE PRETRIAL SCHEDULE

Discovery is scheduled to close on April 1, 2001. 3M proposes that the scheduling order be amended to provide for close of discovery on October 1, 2001; filing of non-dispositive motions on October 1, 2001; filing of dispositive motions on December 1, 2001; and a trial ready date of December 1, 2001. During the remaining discovery period, 3M wants to take two expert depositions and one fact deposition, and to propound additional document requests, interrogatories, and requests for admissions.

Until recently, the basis for 3M's claims was that Maprimed's product literally infringed on 3M's patents. However, now that Alphapharm's sole supplier is Merck, 3M will attempt to prove that Merck's product infringes under the doctrine of equivalents, not literally. Consequently, 3M must prove a different theory of infringement by showing that every limitation of the asserted claims not literally present in the Merck process is present as an equivalent serving substantially the same function in substantially the same way to produce substantially the same result. See Upjohn Co. v. Mova Pharm. Corp., 225 F.3d 1306, 1309 (Fed. Cir. 2000) (citations omitted). To prove the foregoing, 3M wants information about Merck's processes to manufacture flecainide acetate, Merck's reasons for choosing to use particular manufacturing processes, costs associated with the manufacturing processes, research

and development related to the development of the processes, and any alternative processes considered by Merck.²

A request to modify a pretrial scheduling order requires a showing of good cause by the moving party. See D. Minn. LR 16.3. In the present case, the Court finds good cause exists to modify the schedule because Alphapharm recently dropped one supplier and added another in its ANDA. The change in suppliers will affect 3M's claims, and it is entitled to conduct discovery with respect to Merck. The Court does not agree with Alphapharm that 3M should have begun discovery on Merck in May 2000; 3M was entitled to wait until Alphapharm actually added Merck to the ANDA in September 2000 before embarking on discovery. While 3M arguably should have commenced discovery on Merck at that time, the Court accepts 3M's explanation that it remained focused on Maprimed because of the relatively straightforward claim of literal infringement. During discovery thus far, 3M has not conducted itself so as to warrant preclusion of discovery of Merck.

In light of the above, the Court orders the dates in the pretrial scheduling order to be extended by three months. At the hearing, counsel for 3M indicated that a three month extension in the pretrial schedule would not be objectionable. Accordingly, discovery will close on July 1, 2001; non-dispositive motions are due by July 1, 2001; dispositive motions are due by September 1, 2001; and the case will be

² The Court takes no position at this time on whether specific information is relevant or discoverable.

trial ready on September 1, 2001. With respect to Alphapharm's concern that the extension will delay its summary judgment motion, the Court reminds Alphapharm that it may file that motion at any time before September 1, 2001.

III. EXTENSION OF THE 30-MONTH STAY

Neither party advised the Court of the date on which the 30-month stay will expire although 3M's memorandum implies July 4, 2001. (Pl. Mem. Supp. Mot. Extend Dates at 3). In support of its motion, 3M argues that the purpose of the 30-month stay of FDA approval of Alphapharm's ANDA is to preserve the status quo until any infringement litigation is resolved, citing Bristol Myers Squibb Co. v. Royce Lab., Inc., 69 F.3d 1130, 1138 n.5 (Fed. Cir. 1995). At the hearing, 3M also provided the Court with a recently issued, although unpublished, decision in which the District Court for the Southern District of Indiana extended the 30-month stay because the alleged infringer failed to reasonably cooperate in expediting discovery. See Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., No. IP99-0038-C-H/G, 2001 WL 238090, at *1 (S.D. Ind. Mar. 8, 2001).

Alphapharm submits that no other court has ever granted an extension of the 30-month stay, citing Zeneca Ltd. v. Pharmachemie B.V., 16 F. Supp. 2d 112 (D. Mass. 1998), for the proposition that Congress considered the possibility of the statutory bar expiring before the litigation was resolved but rejected imposing stays coincident with

the period of litigation. See id. at 116 (stating “[t]hat the statutory bar might expire prior to a ruling on the validity of the patent was anticipated and accepted by legislators . . .”). In addition, Alphapharm explains if a company were to begin marketing its product upon expiration of a stay and it is later found to have infringed, it will be liable to the patent owner for damages. Alphapharm provides legislative history in support of its assertion that subsequent damages, not an extension of the stay, would be the proper remedy. See H.R. Rep. No. 98-857, pt. 2, at 9 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2694. Finally, Alphapharm submits that 3M’s request for an unlimited extension of the stay is essentially an improperly brought request for a preliminary injunction, and cites Zeneca, 16 F. Supp. 2d at 116, for its holding that a preliminary injunction is the appropriate practice by which to essentially extend the 30-month stay.

The Court finds Eli Lilly conclusively distinguishable from the instant case. In Eli Lilly, the alleged infringer, Zenith, failed to meet the scheduled deadline for serving its expert witness reports on the central issue of that case. See 2001 WL 238090 at *1. The reports were due ninety days before trial, but Zenith could not produce the reports until thirty days before trial. See id. Zenith also caused “[m]uch of the delay” by filing a “belated motion to bifurcate the trial.” Id. In the case at bar, the Court finds no such conduct on behalf of Alphapharm. Alphapharm has followed the pretrial schedule and has not filed

untimely motions for the purpose of delay. Although Alphapharm incidentally caused delay when it challenged discovery requests and amended its ANDA, the Court finds these actions legally supportable, and there are insufficient grounds to conclude that Alphapharm took these actions for the improper purpose of delaying litigation. At present, it is actually 3M that seeks to delay litigation, although not unreasonably, by extending the pretrial deadlines. Furthermore, the Court declines to follow Eli Lilly because there is no consideration by that court of legislative history or alternative solutions such as a permanent injunction or subsequent damages.

In addition, 21 U.S.C. § 355(j)(5)(B)(iii)(III) allows a court to extend the 30-month period only if a party fails to “reasonably cooperate in expediting the action.” Here, the Court finds no such conduct by Alphapharm at this time. Section 355(j)(5)(B)(iii)(III) provides that a court may grant a preliminary injunction even in the absence of unreasonable

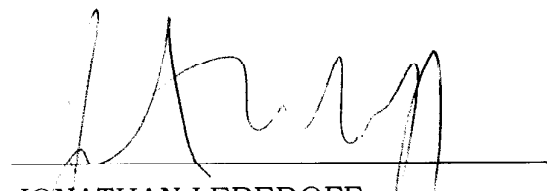
conduct. The statute gives 3M avenues of relief, but an extension of the 30-month stay is not warranted. Consequently, this aspect of Plaintiffs' motion is denied.

Based upon the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED:**

(1) Plaintiffs' Motion to Extend Dates (Doc. No. 92) is **GRANTED** as to modifying the Pretrial Order and **DENIED** as to extending the 30-month stay.

(2) The Pretrial Order is amended as follows: discovery will close on July 1, 2001; non-dispositive motions must be filed prior to July 1, 2001; dispositive motions must be noticed, served, filed, and heard prior to September 1, 2001; and the case will be considered ready for trial as of September 1, 2001. All other provisions of the Pretrial Order shall remain in full force and effect.

Dated: April 2, 2001



JONATHAN LEBEDOFF
United States Magistrate Judge